Complete Summary

GUIDELINE TITLE

The role of single-agent docetaxel (Taxotere®) as a second-line treatment for advanced non-small-cell lung cancer.

BIBLIOGRAPHIC SOURCE(S)

Cancer Care Ontario Practice Guideline Initiative (CCOPGI). The role of single-agent docetaxel (Taxotere) as a second-line treatment for advanced non-small-cell lung cancer [full report]. Toronto (ON): CCOPGI; 2001 Jan. Various p. (Practice guideline report; no. 7-7-2). [16 references]

Logan D, Laurie S, Markman BR, McNeil M, Vincent M, Evans WK, Lung Cancer Disease Site Group. The role of single-agent docetaxel as second-line treatment for advanced non-small-cell lung cancer. Curr Oncol 2001;8(2):50-9. [16 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Advanced non-small-cell lung cancer

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations for the use of docetaxel as second-line chemotherapy for patients with advanced or metastatic non-small-cell lung cancer that is resistant to platinum-based combination chemotherapy

TARGET POPULATION

Adult patients with advanced or metastatic non-small-cell lung cancer (NSCLC) that has become resistant to platinum-based combination chemotherapy

INTERVENTIONS AND PRACTICES CONSIDERED

Single-agent docetaxel (Taxotere®) as a second-line chemotherapy

MAJOR OUTCOMES CONSIDERED

- Survival
- Response rate
- Quality of life
- Progression-free survival
- Disease related symptoms
- Toxicity (adverse effects of treatment)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE (1985 through September 2000), CANCERLIT (1985 through September 2000) and the Cochrane Library (2000 Issue 3) databases were searched. "Carcinoma, non-small-cell" (Medical subject heading (MeSH)) was combined with each of the following words or phrases used as text words: "non small cell lung cancer", "docetaxel", and "taxotere". These terms were then combined with the search terms for the following study designs: practice guidelines, systematic reviews or meta-analyses, randomized controlled trials, and controlled clinical trials. In addition, the Physician Data Query (PDQ) clinical trials database available from the U.S. National Cancer Institute (NCI), and the proceedings of the American Society of Clinical Oncology for 1993 through 2000 were searched for reports of new or on-going trials. Relevant articles and abstracts were selected and reviewed by five reviewers and the reference lists from these sources were searched for additional trials, as were the reference lists from relevant review articles.

Inclusion Criteria

Articles were selected for inclusion in this systematic review of the evidence if they met the following criteria:

1. Randomized controlled trials comparing single-agent docetaxel with either supportive care or another chemotherapy regimen in patients with advanced non-small-cell lung cancer previously treated with platinum-based chemotherapy.
2. Phase II trials of single-agent docetaxel as second-line chemotherapy in patients with advanced non-small-cell lung cancer previously treated with platinum-based chemotherapy. Trials that enrolled both chemotherapy-naïve and platinum-pretreated patients were included if the results were reported separately for the two groups of patients.
3. Articles published as full reports or as abstracts were considered.

Exclusion Criteria

1. Studies in which docetaxel followed a first-line chemotherapy which was not platinum-based were excluded.
2. Letters and editorials were not considered.
3. Papers published in a language other than English were not considered, unless they had an English abstract.

NUMBER OF SOURCE DOCUMENTS

Two randomized controlled trials and eleven phase II trials

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesizing the Evidence

The Lung Disease Site Group decided not to pool the data from the randomized controlled trials because there were only two trials and they used different control conditions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The initial draft of the guideline was based on the evidence from randomized trials presented in two abstracts. Many members of the Lung Disease Site Group (DSG) felt that it was premature to make recommendations prior to the availability of full publication of these trials. The Lung DSG did have access to a preprint of one study and the principal investigator of that trial was a member of the Lung DSG. This was handled through full disclosure. All members of the Lung DSG were aware of the potential conflict of interest position that existed for the principal investigator on the Lung DSG. Members were careful to ensure that data from the trial was presented to them objectively and completely. This trial has since been published by Dr. Shepherd as has the second trial. The fully published data are consistent with the data in the abstracts and the recommendation remains unchanged. The members of the Lung DSG felt it was important that the guideline recommend a dose of 75 mg/m^2 of docetaxel, based on the Shepherd study.

The draft recommendations that were sent out for practitioner feedback contained two qualifying statements that indicated docetaxel was not recommended as first-line therapy and that there was insufficient evidence to recommend combination chemotherapy containing docetaxel as second-line therapy. These statements were removed after practitioner feedback had been completed, as the Lung DSG recognized that they were not relevant to the guideline question and that the literature search strategy had not addressed either of these issues.

The Lung DSG discussed whether there were specific subsets of patients who would be more likely to respond to docetaxel. It was concluded that there was insufficient evidence to make any recommendations on the population most likely to benefit from treatment with docetaxel as second-line therapy. There was also a lack of evidence about when docetaxel should be used for "cisplatin-resistant" patients. The clinical trials that were reviewed had accepted patients who were either progressing on cisplatin or who had progressed after receiving cisplatin therapy. It was recognized that more patients are receiving chemotherapy as part of combined modality therapy for stage III disease. If these patients develop metastatic disease many months after receiving combined modality therapy, it was felt that re-treatment with the initial chemotherapy would probably be the best strategy, rather than immediately proceeding to use docetaxel as second-line therapy. Lung DSG members recognized that there is little or no data to inform this decision and suggested that this would be a useful area for clinical investigation.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practitioner feedback was obtained through a mailed survey of 37 medical oncologists in Ontario. The survey consisted of 21 items evaluating the methods, results, and interpretive summary used to inform the draft recommendations outlined and whether the draft recommendations above should be approved as a practice guideline. Written comments were invited. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The Lung Disease Site Group reviewed the results of the survey.

Final approval of the original guideline report was obtained from the Practice Guidelines Coordinating Committee (PGCC).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- If survival is the main outcome of interest for a patient who is a candidate for second-line therapy, it is reasonable to offer docetaxel at 75 mg/m^2 every three weeks to medically suitable patients, with a full discussion of the benefits, limitations, and toxicities.
- If quality of life is the outcome of interest for a patient who is a candidate for second-line therapy, single-agent docetaxel is an option that may result in improved quality of life and reduced disease-related symptoms when compared with best supportive care.
- Alternate options that should be discussed with a candidate for second-line therapy would include supportive care or a clinical trial involving a new agent or regimen.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The following were eligible for inclusion in the systematic review of the literature: two randomized controlled trials, one of which was associated with a companion report on quality of life published in abstract form, comparing single-agent docetaxel to best supportive care or to other single-agent chemotherapy regimens in patients with advanced non-small-cell lung cancer previously treated with platinum-based chemotherapy; eleven phase II trials of single-agent docetaxel, four fully published and seven published in abstract form.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- There is evidence from two randomized controlled trials of a benefit in overall survival and progression-free survival when docetaxel (Taxotere®) is used as a second-line treatment in patients with good performance status and advanced non-small-cell lung cancer (NSCLC) resistant to platinum-based combination chemotherapy. Docetaxel at 75 mg/m^2 was associated with improved survival (median survival, 7.5 versus 4.6 months; p=0.010 log rank) and one-year overall survival (37% versus 12%; p=0.003 chi-square), when compared with best supportive care. In a second randomized controlled trial, a survival advantage with this dose of docetaxel was also detected over second-line single-agent therapy with either vinorelbine or ifosfamide (one-year overall survival, 32% versus 19%; p=0.025 chi-square). In addition, progression-free survival at 26 weeks was superior for patients receiving docetaxel 100 mg/m^2 (p=0.013 chi-square) and 75 mg/m^2 (p=0.031 chi-square) when compared with vinorelbine/ifosfamide and progression-free survival for the two docetaxel arms pooled was significantly longer than vinorelbine or ifosfamide (p=0.005 chi-square).
- Docetaxel at 100 mg/m^2 every three weeks was associated with improvement in several parameters of quality of life when compared with either best supportive care or vinorelbine/ifosfamide.

POTENTIAL HARMS

Neutropenia was the major toxicity seen in all studies in which toxicity data were presented. One trial of lower-dose docetaxel administered every three weeks showed response rates and median survival similar to those obtained for higher-dose docetaxel, but without any episodes of febrile neutropenia, an event that occurred in up to 16% of patients in the remaining trials.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Cancer Care Ontario Practice Guideline Initiative (CCOPGI). The role of single-agent docetaxel (Taxotere) as a second-line treatment for advanced non-small-cell lung cancer [full report]. Toronto (ON): CCOPGI; 2001 Jan. Various p. (Practice guideline report; no. 7-7-2). [16 references]

Logan D, Laurie S, Markman BR, McNeil M, Vincent M, Evans WK, Lung Cancer Disease Site Group. The role of single-agent docetaxel as second-line treatment for advanced non-small-cell lung cancer. Curr Oncol 2001;8(2):50-9. [16 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan 17

GUIDELINE DEVELOPER(S)

Practice Guidelines Initiative - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Practice Guidelines Initiative (PGI) is the main project of the Program in Evidence-based Care (PEBC), a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario, Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Provincial Lung Cancer Disease Site Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The Lung Disease Site Group comprises medical and radiation oncologists, pathologists, surgeons, epidemiologists, a psychologist, a medical sociologist, and community representatives.

Group Members: Dr. William K. Evans (Chair); Dr. Yasmin Alam; *Dr. Barbara Campling; Dr. Gail Darling; Dr. Peter Dixon; Dr. Ron Feld; *Dr. Brian Findlay; Dr. Glen Goss; Dr. Ian Graham; Dr. Richard Gregg; *Dr. Neill Iscoe; Dr. Walter Kocha; *Dr. Arnost Kolin; Dr. Jaro Kotalik; Dr. Scott Laurie; *Dr. Catherine Lochrin; Dr. Diane Logan; Dr. Pedro Lopez; Dr. Richard Malthaner; Dr. Donna Maziak; *Dr. Andrew McIvor; Dr. John Miller; Dr. Gordon Okawara; *Dr. James Rusthoven; Dr. Frances Shepherd; Dr. David Stewart; Dr. Yee Chung Ung; *Dr. John Urschel; Dr. Mark Vincent; *Dr. Georg Wenckebach; Dr. Edward Yu.

Resource group members working with the Lung Disease Site Group: Faculty: Dr. Michael Brundage; Staff: Angela Eady, *Anna Gagliardi, Barbara R. Markman.

*Members that have completed term with the Lung Cancer Disease Site Group

For a current list of members, please see the Cancer Care Ontario Web site.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Lung Cancer Disease Site Group disclosed potential conflict of interest information.

GUIDELINE STATUS

This is the current release of the guideline.

The guideline developer instituted a new format for their guidelines and evidence summaries: A SUMMARY of the original Practice Guideline or Evidence Summary, integrated with the most current information, replaces the ABSTRACT, RECOMMENDATION, BRIEF REPORT and EVIDENCE UPDATE.

The FULL REPORT, initially the full original Guideline or Evidence Summary, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The role of single-agent docetaxel (Taxotere®) as a second-line treatment for advanced non-small-cell lung cancer. Summary. Toronto (ON): Cancer Care Ontario (CCO), 2001 Jan. Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 19, 2002. The information was verified by the guideline developer on August 19, 2002.

COPYRIGHT STATEMENT

Date Modified: 11/8/2004